

**What is claimed is:**

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1. A whole blood immunoassay comprising the steps of:  
mixing a whole blood sample with sensitized insoluble  
carrier particles to cause an immune agglutination;
- 5 diluting the resulting agglutination mixture with an  
aqueous solution containing an erythrocyte lysing agent to lyse  
erythrocytes, thereby preparing an assay sample; and  
determining a degree of agglutination of the assay  
sample.
- 10 2. A whole blood immunoassay according to Claim 1,  
wherein the erythrocyte lysing agent is a surfactant.
3. A whole blood immunoassay according to Claim 2,  
wherein the surfactant is sodium dodecyl sulfate.
4. An whole blood immunoassay according to Claim 1
- 15 which is conducted by use of an apparatus for a counting  
immunoassay utilizing a principle of flow cytometry.
5. A whole blood immunoassay according to Claim 4,  
further comprising the steps of:  
introducing the assay sample included unagglutinated
- 20 particles and agglutinated particles to a flow cell, irradiating  
particles passing through the flow cell with laser light, and  
detecting scattered light generated thereby;  
setting a threshold value for distinguishing  
unagglutinated particles from agglutinated particles with
- 25 regard to intensity of the scattered light; and
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distinguishing and counting the unagglutinated particles and the agglutinated particles in reference to the threshold value, and

calculating the degree of agglutination from the number of unagglutinated particles and the number of agglutinated particles.

6. A whole blood immunoassay according to Claim 5, wherein the degree of agglutination is calculated by the number of agglutinated particles P / (the number of agglutinated particles P + the number of unagglutinated particles M).

7. A whole blood immunoassay according to Claim 5, wherein the scattered light is forward scattered light.

8. A whole blood immunoassay according to Claim 1, wherein the size of the insoluble carrier particles is  $0.1 \mu\text{m}$  to  $20 \mu\text{m}$ .

9. A whole blood immunoassay according to Claim 1, wherein a mixture ratio of the whole blood sample to the insoluble carrier particles is 1 : 5 to 1 : 20.

10. An immunoassay according to Claim 1, wherein, in the immune agglutination of the whole blood sample with the insoluble carrier particles, the reaction temperature is from 20 to  $50^\circ\text{C}$  and the reaction time is from 15 seconds to 20 minutes.